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Pesticide Fact Sheet Number 235: 'Bacillus subtilis' GB03

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EPA, Office of Pesticide Programs, Registration Division

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U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (H7505C)
401 M Street, SW
Washington, D.C. 20460

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This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

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Office of Pesticide Programs (TS-766C)
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EPA

Pesticide Fact Sheet

PB92-238484

Name of Chemical: Bacillus subtilis GB03
Reason for Issuance: Registration of New Biological Fungicide
Date Issued: July 9, 1992
Fact Sheet Number: 235

DESCRIPTION OF CHEMICAL

Generic Name: Bacillus subtilis GB03

Trade Name: Gus 2000 Biological Fungicide

EPA Shaughnessy Code: 129068-3

Year of Initial Registration: 1992

Pesticide Type: Biological Fungicide

U.S. and Foreign Producers: Gustafson, Inc.

USE PATTERNS AND FORMULATIONS

APPLICATION SITES: Seed treatment only. The product may be used on all crop seeds.

METHOD OF APPLICATION: Application may be made by mixing with seed in the planter box at the time of planting or by using standard on-farm slurry treating equipment.

TYPE OF FORMULATION: 2.75% powder formulation containing not less than 5.5×10^{10} viable Bacillus subtilis spores/gram.

APPLICATION RATES: Application rates range from 2 to 4 ounces/100 pounds of seed.

SCIENCE FINDINGS

Summary Science Statement

The results of the toxicity/pathogenicity studies submitted indicated that the product was not toxic, pathogenic, or infective to test animals when applied by oral, dermal, intratracheal or intravenous methods of application. Primary eye irritation placed the product in Toxicity category III (Caution). No reports of hypersensitivity were reported.

Requests for waiver of requirements for testing of avian (aquatic), aquatic organisms, non-target insect and honey bees were granted. Non-target plant studies indicated that Bacillus subtilis GBO3 was not pathogenic to soybean seed. A request for waiver of testing requirements for terrestrial avian species was denied. As a condition of registration, the registrant must submit the results of an acute avian oral study using bobwhite quail within one year of registration. The product will not pose a risk to wild mammalian species.

Data for environmental fate are not triggered under current requirements for the proposed product since the organism is a naturally occurring species and the results of initial Tier I tests did not trigger the need for additional testing.

CHEMICAL CHARACTERISTICS

Physical/Chemical Properties

Color:	Buff/yellow-cream
Physical State:	Powder
Odor:	Musty, cheese-like
Bulk Density:	31-34 lbs/ft^3
pH:	4.8
Storage Stability:	30 days

TOXICOLOGICAL CHARACTERISTICS

Acute oral toxicity/pathogenicity test: It was concluded from the results of this test that the product was not toxic or infective to rats when given an oral dose containing Bacillus subtilis at 1.9×10^8 colony-forming units (CFU) per animal.

Acute dermal toxicity: A single 2 gram/animal dose (3.6×10^9 CFU) administered dermally to rabbits was not toxic. The product would be in Toxicity category IV for dermal effects.

Acute pulmonary toxicity/pathogenicity: The product was not toxic, pathogenic or infective to rats dosed intratracheally with 2.84×10^8 CFU of test material.

Acute intravenous toxicity/pathogenicity: When rats were dosed intravenously with 1.8×10^7 CFU of test material, the product was not infective, pathogenic or toxic to the animals.

Primary Eye Irritation: The product produced slight to severe ocular irritation when a single 0.1 gram ocular dose was administered which dissipated within 7 days after dosing. The product is in Toxicity category III (Caution) for eye irritation.

Hypersensitivity: No reports of hypersensitivity were reported from personnel working with this organism.

ECOLOGICAL CHARACTERISTICS

The avian acute testing requirement for Mallard duck was waived because of natural occurrence of the organism and the lack of aquatic exposure from a seed treatment use. Testing requirements for other aquatic organisms were also waived for these reasons and there are no reports of pathogenicity or toxicity of Bacillus subtilis to aquatic species in the public literature.

Based upon lack of toxicity, pathogenicity and infectivity to rats, the product should not pose a risk to wild mammalian species. Studies on non-target insects and honey bees were waived because of lack of exposure of insects to the product from seed treatment.

There have been published reports indicating the Bacillus subtilis may cause seed decay in soybeans so data were requested to demonstrate the lack of pathogenicity or phytotoxicity of the product when applied to soybean seed. Results of the tests showed that there was no effect on the number of germinated seedlings produced after 8 days from seed treated with the product. It was concluded that this bacterial strain is not a seed decay organism.

A request for waiver of testing on terrestrial avian species was requested. This waiver was denied. The registrant will be required to submit an acute avian oral study using bobwhite quail because of potential exposure of birds from ingesting treated seeds.

It was concluded that no risk to endangered avian (aquatic), aquatic, plant or insect species is expected from the use of this product because of lack of documented toxicity and little, if any, exposure. The possibility of risk to endangered terrestrial avian species will be evaluated upon receipt of the results from the requested avian oral toxicity test.

BENEFITS

The bacteria in the product, when applied to seeds, colonize the developing root system of the plant and compete with disease organisms which attack roots. The bacteria continue to live on the root system and extends protection throughout the growing season. The protection afforded by the bacteria will allow the plants to establish a vigorous root system which generally results in a more uniform stand and more vigorous plants. Since Bacillus subtilis is a spore-forming bacterium, the product is more stable than other bacterial pesticides and viability is retained even if treated seed is stored for prolonged periods.

This biological fungicide may be an effective alternative to chemical seed treatment fungicides and therefore could replace more hazardous products. Because the bacteria continue protection throughout the growing season, the need for additional post-

planting applications of chemical fungicides to control soil-borne plant pathogens of roots may be reduced or eliminated.

TOLERANCE ASSESSMENT

An exemption from the requirement of a tolerance is proposed to be established for the residues of Bacillus subtilis strain GB03 in or on all raw agricultural commodities when applied as a seed treatment for growing agricultural crops in accordance with good agricultural practices. Based upon the lack of toxicity of this organism in the Tier 1 mammalian toxicity/pathogenicity studies, an exemption from tolerance requirements is warranted. Also, the organism would be destroyed by heat during cooking and would be removed from produce by normal cleaning and washing operations prior to consumption or processing.

SUMMARY OF MAJOR DATA GAPS

The only outstanding data gap for this biological fungicide is the requirement for conducting an acute oral toxicity/pathogenicity study using bobwhite quail. This study is being required because birds may be exposed to the product by ingesting treated seeds. There have been no reports of pathogenicity of Bacillus subtilis to avian species in the public literature, so the risk posed to terrestrial avian species would appear to be minimal. As an added precaution, labeling requires that spilled seed or seed exposed on the soil surface be incorporated or covered with soil. A conditional registration would, therefore, be justified while the data are being developed. Protocols for the proposed testing have been submitted and found to be acceptable.

CONTACT PERSON AT EPA

Susan T. Lewis,
Product Manager (PM) 21,
Registration Division (H-7505C),
Environmental Protection Agency,
401 M Street, SW,
Washington, D.C. 20460

Office location and telephone number:
Rm. 227, CM#2,
1921 Jefferson Davis Highway,
Arlington, VA 22202.
(703) 305-1900.

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